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DRAWINGS ATTACHED.

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## COMPLETE SPECIFICATION.

## Improvements in and relating to Catheter Devices.

We, NATIONAL RESEARCH DEVELOPMENT Corporation established by statute, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to catheters and means for packaging them so as to enable maintainance of their sterility prior to their introduction into a patient.

Catheters for tracheal or urethral drainage may be supplied in a sterile condition, for example sealed in a plastic bag, but are nevertheless liable to contamination prior to their introduction into a patient by contact with the patient, the surgeon and the atmosphere; in order to minimise risk of contamination elaborate precautions may be prescribed for the sterilization of the hands or gloves of the surgeon and for covering, for example by sterile towelling, parts of the patient which are liable to be contacted by a catheter immediately prior to its insertion which may take place so far as is practicable in sterile surroundings.

When, despite prophylactic precautions, internal infection of a patient occurs this may be counteracted by administration of antibiotic drugs over a period of time often exceeding a week.

An object of the invention is to provide means for the introduction of a catheter into a patient with minimum risk of impairing its sterile condition for infecting the patient.

According to the invention a catheter device comprises an annular connector, one

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end region of which is connected to one end of a protective tube of flexible sheet material, the other end of which protective tube is connected to an end region of a catheter tube which lies normally inside the protective tube and the connector.

The annular connector preferably has a flange adjacent the protective tube and the flange may extend around a shank of the connector a sufficient distance to shield apertures in the shank which communicate with its interior.

The catheter device is preferably supplied in an enclosing bag and sterilized as by irradiation or ethylene oxide.

The invention also includes a penis adapter for male urethrocatheterization comprising a sleeve of flexible material connected at one end to a socket for receiving the annular connector of the catheter device. The parts may be made of plastics material such as polyethylene and may be disposable.

Reference should now be made to the accompanying drawings in which:—

Fig. 1 is a side sectional view of a catheter device with connector.

Fig. 2 is a section of a tracheostomy tube used with the catheter device.

Fig. 3 is a section showing the end of the catheter device inserted in the tracheostomy tube.

Fig. 4 shows an alternative arrangement of a connector with different breathing arrangements, and

Fig. 5 shows a urethral adaptor for receiving the catheter device.

The arrangement shown in Figs. 1, 2 and 3 is that of a catheter device used for tracheal drainage. The device consists

of an annular connector 1 having a concentric hole 2 with radial holes 3 and a collar 4. There is a suction catheter 5 enclosed in a flexible plastic protective tube 6, the tube being fastened to the catheter at one end with a rubber band 7 and to the connector at the other end by a further rubber band 8. The catheter 5 is hollow and is provided with transverse holes 9 communicating with the interior of the catheter.

The connector is adapted to be inserted in a tracheostomy tube 10 which has a flange 11 to receive the end of the connector, the two when assembled being mutually arranged as shown in Figure 3. From this it will be seen that the patient can breathe along the hole 2 with communication to the outer atmosphere via the holes 3. The collar 4 acts as a protection against contamination of the outer edges of the air holes 3 by the fingers of a surgeon or nurse.

When the connector is inserted in the tracheostomy tube flange, the catheter 5 can be pushed down into the tracheostomy tube and hence into the lung of the patient, by the collapse and/or concertina folding of the protective tube 6. Preferably the catheter itself is made of some flexible plastic material such as polythene or polyvinylchloride, and the interior of the tracheostomy tube may be lubricated in order to ensure that the catheter glides smoothly into position down the tube.

The catheter, connector and protective tube are sealed in a flexible bag 12 after manufacture, the interior of which is sterilized, for example, either by irradiation or by inclusion of ethylene oxide in the flexible bag. Before use, the flexible bag is ruptured and removed, leaving the catheter itself and its connector in a substantially sterilized condition ready for use. After use, the catheter may be re-sterilized, or may be disposed of.

It should be noted that the catheter tube does not contact the surgeon or nurse, since its forward end does not normally extend beyond the end of the connector. The catheter tube end is advanced through the connector and the tracheostomy tube, without any direct contact with the surgeon, or without being exposed to the exterior atmosphere.

Where the patient is breathing through a respirator having a connector connected with the flange 11 of a tracheostomy tube, tracheal toilet of the patient may be performed without disconnection of the respirator if a suitable respirator connector, viz. a T-junction connector having an opening having the same form and dimensions as, and in alignment with, the opening of the tracheostomy tube, is employed. This additional opening of the respirator con-

connector would be normally closed by a removable plug, the plug being simply removed and the connector 1 of the catheter device inserted when tracheal toilet is required.

Figure 4 shows an alternative form of connector. This connector consists of a central tube 20 which terminates in a collar 21, the collar being pierced with a number of holes 22 communicating with the outer air at one end and with the inside of the plastic envelope at the other. A tracheostomy tube may be fitted to the end of the tube 20 as in the first embodiment. The patient breathes by air inspired and expired through the tube 20 and the plastic envelope, this air communicating with the outer atmosphere through the holes 22. Preferably there is a shield 23 to divert the patient's breath from the tracheostomy wound and the tracheostomy tube itself. As an alternative to this arrangement, the connector may consist of two concentric tubes, one as shown at 20, and an exterior tube, with flanges or breathing channels made of further tubes spacing one from the other. The exact form of connector will be dictated by the method of manufacture to be used.

For urethral drainage we provide an adaptor Fig. 5, which is arranged to be fitted over the patient. The adaptor consists of a collar 30 which is shaped so as to fit over the end of an annular connector of a catheter, the connector having no air holes. The collar 30 is provided with a flexible plastic sleeve 31, fastened to a ring 32 of resilient material which is fitted over the penis of the patient. The advantage of this device is that the surgeon is able manually to manipulate the advance of the catheter tube by grasping it through the plastic sleeve, thus facilitating its progress past obstructions caused for example by a swollen or cancerous prostate gland, in a way that is impossible when using forceps in order to reduce risk of contamination.

Various other adaptors may be employed in connection with a catheter according to the invention, the form of catheter tube being determined by the nature of the organ or portion of the body to which it is to be applied.

Various modifications may be made to our invention. Thus for example the connector itself may be made without any flange over the air holes, but with a long connector tube protruding from the plastic bag, with radial air holes near the end of the tube remote from the bag. Again, the catheter connector itself may be made of material such as nylon to reduce the coefficient of friction between the catheter and the connector. This is particularly important whilst moving the catheter tube in

when changing from one lung to another. Finally, the device may readily be used in conjunction with a closed respiratory system, adapted to receive a patient's breath, sterilize it, add any necessary oxygen and remove carbon dioxide and then recirculate the air to the patient.

The connector may be fastened to its tracheostomy tube by means such as a bayonet joint.

#### WHAT WE CLAIM IS:—

1. A catheter device comprising an annular connector, one end region of which is connected to one end of a protective tube of flexible sheet material, the other end of which protective tube is connected to an end region of a catheter tube which lies normally inside the protective tube and the connector.

2. A catheter device as claimed in claim 1 in which the connector has a flange adjacent the protective tube, the flange extending round the connector so as to shield apertures in the shank of the connector communicating with its interior.

3. A catheter device as claimed in claim 1, provided in a sealed enclosing bag the

interior of which, including the catheter tube, is sterilized.

4. A catheter device as claimed in any one of the preceding claims in which at least the catheter tube itself is made from a flexible plastics material such as polyethylene.

5. A catheter device as claimed in any one of the preceding claims, adapted for tracheostomy drainage.

6. A catheter device as claimed in any one of claims 1 to 4, adapted for male urethro-catheterisation.

7. A catheter device as claimed in claim 1, wherein the connector defines breathing apertures therethrough in the direction of its length.

8. A catheter device as claimed in any one of the preceding claims, substantially as described with reference to the accompanying drawings.

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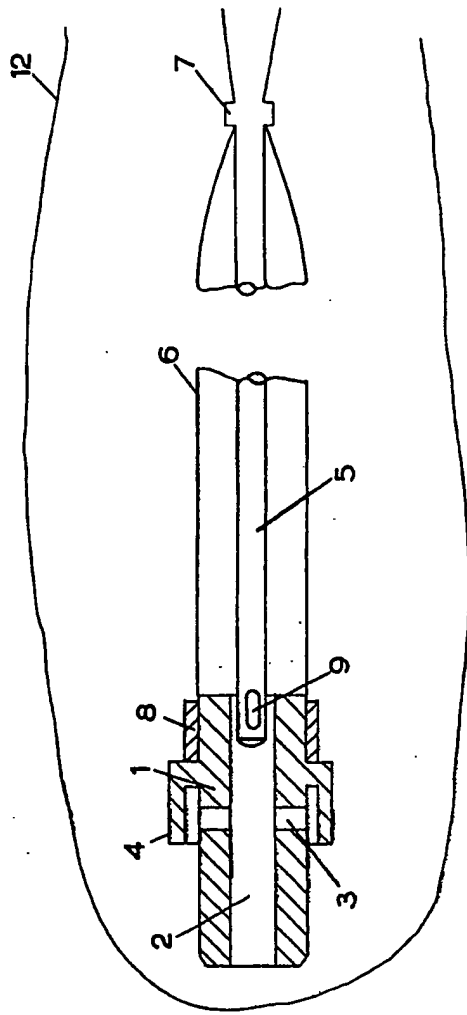


FIG. 1.

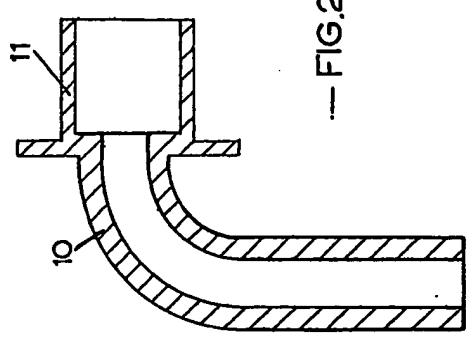


FIG. 2.

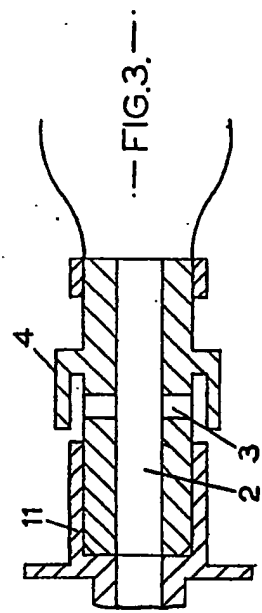
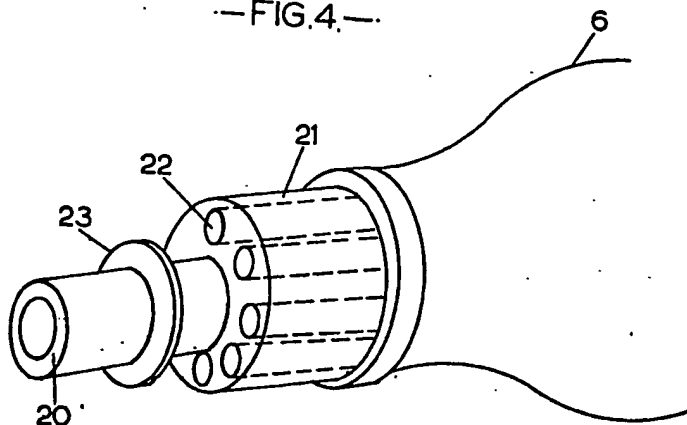


FIG. 3.

—FIG.4.—



—FIG.5.—

